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**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY**

PURDUE PHARMACEUTICAL
PRODUCTS L.P.; PURDUE PHARMA L.P.;
and PURDUE PHARMA TECHNOLOGIES
INC.,

Plaintiffs,

v.

LANNETT HOLDINGS, INC. and
LANNETT COMPANY, INC.,

Defendants.

Civil Action No. 2:15-cv-06036-SDW-LDW

**DEFENDANTS LANNETT HOLDINGS, INC. AND LANNETT COMPANY, INC.'S
ANSWER, DEFENSES, AND COUNTERCLAIMS**

Defendants, Lannett Holdings, Inc. and Lannett Company, Inc. (collectively “Lannett” or “Defendants”), answers the Complaint filed by Purdue Pharmaceutical Products L.P.; Purdue Pharma L.P.; and Purdue Pharma Technologies Inc. (collectively “Purdue” or “Plaintiffs”), and sets forth its defenses and counterclaims, as follows:

The Parties

1. Lannett lacks knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 1, and therefore denies these allegations.
2. Lannett lacks knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 2, and therefore denies these allegations.
3. Lannett lacks knowledge or information sufficient to form a belief as to the truth

of the allegations set forth in paragraph 3, and therefore denies these allegations.

4. Lannett admits that Lannett Holdings, Inc. is a corporation organized and existing under the laws of the State of Delaware. Any remaining allegations in paragraph 4 are conclusions of law to which no response is required. To the extent a response is required, Lannett denies any and all other allegations in paragraph 4.

5. Lannett admits that Lannett Company, Inc. is a corporation organized and existing under the laws of the State of Delaware. Any remaining allegations in paragraph 5 are conclusions of law to which no response is required. To the extent a response is required, Lannett denies any and all other allegations in paragraph 5.

6. Admitted.

7. Lannett admits that Lannett Company, Inc. is involved in the manufacture and/or sale of various pharmaceutical products, with business activities in several states, including New Jersey. Lannett also admits that it has prepared and/or aided in the preparation of Abbreviated New Drug Applications (“ANDAs”) for submission to the United States Food and Drug Administration (“FDA”). Lannett denies any and all remaining allegations in paragraph 7.

Nature of Action and Jurisdiction

8. Lannett admits that this purports to be an action arising under the Patent Laws of the United States, Title 35, United States Code, and more particularly under 35 U.S.C. §§ 271 et seq. Lannett admits that Lannett Holdings, Inc. submitted Abbreviated New Drug Application No. 207108 (“the Lannett ANDA”) seeking approval to market Lannett’s Hydromorphone Hydrochloride Oral Solution USP, 5 mg/5 mL (“the Lannett Product”) prior to the expiration of U.S. Patent No. 6,589,960 (“the ‘960 patent”). Lannett admits that paragraph 8 of the complaint invokes the subject matter jurisdiction of this Court based on 28 U.S.C. §§ 1331-1338(a), and

2201, 2202, and 35 U.S.C. § 271. Lannett lacks knowledge or information sufficient to form a belief as to whether the Court has subject matter jurisdiction and therefore denies this allegation. Lannett denies any and all remaining allegations in paragraph 8.

9. Lannett admits that Lannett Company, Inc. markets, sells, and distributes pharmaceutical products in New Jersey and derives revenue from such activities. Lannett denies that Lannett Holdings, Inc. makes, ships, uses, offers to sell, or sells; or causes others to use, offer to sell, or sell pharmaceutical products in New Jersey. Lannett also denies that Lannett Holdings, Inc. has customers in the State of New Jersey. Any remaining allegations in paragraph 9 are conclusions of law to which no response is required. To the extent a response is required, Lannett denies any and all remaining allegations in paragraph 9.

10. Lannett admits that Lannett Company, Inc. holds a manufacturer license in New Jersey, Registration No. 5004020; and has filed income tax returns in Pennsylvania, New Jersey, and California. Lannett admits that Civil Action No. 05-4202 was removed from New Jersey state court to the District of New Jersey in response to a Notice of Removal filed by Lannett Company, Inc., and that Lannett Company, Inc. consented to personal jurisdiction in the District of New Jersey in that action. Lannett also admits that Lannett Holdings, Inc. filed a counterclaim and sought injunctive relief in Civil Action No. 05-4202. Any remaining allegations in paragraph 10 are conclusions of law to which no response is required and/or not sufficiently definite to permit responsive pleading and are therefore denied. To the extent a response is required, Lannett denies any and all remaining allegations in paragraph 10.

11. The allegations in paragraph 11 are conclusions of law for which no response is required. To the extent a response is required, Lannett denies any and all allegations in paragraph 11.

12. Lannett admits that Lannett Holdings, Inc., and Lannett Company, Inc. have certain individuals who are officers in both Lannett Holdings, Inc. and Lannett Company, Inc. To the extent the remaining allegations in paragraph 12 are understood, they are denied and/or are conclusions of law for which no response is required.

13. Denied.

14. Denied.

15. Lannett admits that Lannett Company, Inc. markets, sells, and/or distributes pharmaceutical products in New Jersey. Lannett denies any and all remaining allegations in paragraph 15.

16. The allegations in paragraph 16 are conclusions of law for which no response is required. To the extent a response is required, Lannett denies any and all allegations in paragraph 16.

17. Lannett admits that if and when products are manufactured and sold as a result of FDA approval of the Lannett ANDA, it is possible that New Jersey might be a destination for such products. Lannett denies any and all remaining allegations in paragraph 17.

18. The allegations in paragraph 18 are conclusions of law for which no response is required. To the extent a response is required, Lannett denies any and all allegations in paragraph 18.

19. Lannett consents to this Court's exercise of personal jurisdiction for the purposes of this action. Any remaining allegations in paragraph 19 are conclusions of law to which no response is required. To the extent a response is required, Lannett denies any and all remaining allegations in paragraph 19.

Venue

20. Lannett admits that venue is proper in this District for the purposes of this action.

FACTUAL BACKGROUND

21. Lannett admits the ‘960 patent on its face is entitled “Hydromorphone And Hydrocodone Compositions And Methods for Their Synthesis,” and on its face lists a date of issue by the U.S. Patent and Trademark Office of July 8, 2003. Lannett denies that the ‘960 patent was duly and legally issued. Lannett admits that a copy purporting to be the ‘960 patent was attached to the Complaint as Exhibit A.

22. Lannett lacks knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 22, and therefore denies these allegations.

23. Lannett admits that New Drug Application (“NDA”) No. 19-891 is for the manufacture and sale of Dilaudid[®] (hydromorphone hydrochloride) oral solution (“Dilaudid[®]”). Lannett lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations in paragraph 23, and therefore denies these allegations.

24. Lannett admits that the FDA publication entitled Approved Drug Products with Therapeutic Equivalence Evaluations (commonly known as the “Orange Book”) lists the ‘960 patent as purportedly covering Dilaudid[®].

25. Lannett admits that Lannett Holdings, Inc. submitted Abbreviated New Drug Application No. 207108 to the FDA under § 505(j)(2) of the Federal Food, Drug, and Cosmetic Act seeking approval to manufacture, import, use, offer for sale, and/or sell a generic hydromorphone hydrochloride oral solution product containing 5 mg/5 mL hydromorphone hydrochloride before the expiration of the ‘960 patent. Lannett denies any and all remaining allegations in paragraph 25.

26. Lannett admits that the Lannett ANDA contains a certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) (“Paragraph IV Certification”) alleging that the ‘960 patent is not infringed and/or is invalid.

27. Lannett admits that Lannett Holdings, Inc. sent to Purdue Pharmaceutical Products L.P. a letter (“the Lannett Paragraph IV Notice Letter”) signed by a representative of Lannett Holdings, Inc.; constituting a notice in compliance with 21 U.S.C. § 355(j)(2)(A)(vii)(IV) of the filing by Lannett Holdings, Inc. of ANDA No. 207108; and stating that the Lannett ANDA contains a Paragraph IV Certification regarding the ‘960 patent. Lannett denies any and all remaining allegations in paragraph 27.

28. Lannett admits that the Lannett Paragraph IV Notice Letter states the intention of Lannett Holdings, Inc. to seek approval to market the Lannett Product prior to the expiration of the ‘960 patent. Lannett admits that Lannett Company, Inc. is involved in the marketing and/or sale of products containing hydromorphone hydrochloride in several states, including New Jersey. Lannett denies any and all remaining allegations in paragraph 28.

COUNT I: Infringement of the ‘960 Patent under 35 U.S.C. § 271

29. Lannett restates its answers to the allegations in paragraphs 1-28 and incorporates by reference its responses as if fully set forth herein.

30. Paragraph 30 contains conclusions of law to which no response is required. To the extent a response is required, Lannett denies any and all allegations in paragraph 30.

31. Lannett admits to being aware of the existence of the ‘960 patent prior to the commencement of this action. Any remaining allegations in paragraph 31 are conclusions of law to which no response is required. To the extent a response is required, Lannett denies any and all remaining allegations in paragraph 31.

32. Paragraph 32 contains conclusions of law to which no response is required. To the extent a response is required, Lannett denies any and all allegations in paragraph 32.

LANNETT'S AFFIRMATIVE DEFENSES

Lannett, without prejudice to the denials set forth in its Answer, alleges the following defenses to Plaintiffs' Complaint. Lannett reserves its right to assert additional defenses as it learns more information through discovery.

First Affirmative Defense

1. Lannett has not and will not infringe, directly or indirectly, whether literally or under the doctrine of equivalents, any valid claim of the '960 patent by making, using, selling, offering for sale, or importing into the United States the Lannett Product, nor do Lannett's activities relating to the filing of the Lannett ANDA result in infringement of any valid claim of the '960 patent.

Second Affirmative Defense

2. Each claim of the '960 patent is invalid for failure to comply with one or more of the statutory provisions of 35 U.S.C. §§ 101, *et seq.*, including, but not limited to, §§ 101, 102, 103, and/or 112.

Third Affirmative Defense

3. Plaintiffs' Complaint fails to state a claim upon which relief may be granted.

Fourth Affirmative Defense

4. This Court lacks subject matter jurisdiction over Plaintiffs' patent infringement claims.

Fifth Affirmative Defense

5. Lannett Company, Inc. is not a proper party to this action.

COUNTERCLAIMS

As separate and independent Counterclaims against Plaintiffs, Lannett alleges as follows:

The Parties

1. Lannett Holdings, Inc. is a corporation organized and existing under the laws of the State of Delaware having a place of business at 103 Foulk Road, Suite 202, Wilmington, DE 19803.

2. Lannett Company, Inc. is a corporation organized and existing under the laws of the State of Delaware having a place of business at 13200 Townsend Road, Philadelphia, PA 19154.

3. Upon information and belief, Plaintiff/Counterclaim-Defendant Purdue Pharmaceutical Products L.P. is a Delaware limited partnership having a place of business at One Stamford Forum, 201 Tresser Boulevard, Stamford, Connecticut 06901-3431.

4. Upon information and belief, Plaintiff/Counterclaim-Defendant Purdue Pharma L.P. is a Delaware limited partnership having a place of business at One Stamford Forum, 201 Tresser Boulevard, Stamford, Connecticut 06901-3431. Upon information and belief, Purdue Pharma L.P. and/or its affiliates own, lease, and maintain several facilities in the State of New Jersey.

5. Upon information and belief, Plaintiff/Counterclaim-Defendant Purdue Pharma Technologies Inc. is a Delaware corporation having a place of business at One Stamford Forum, 201 Tresser Boulevard, Stamford, Connecticut 06901-3431.

Jurisdiction and Venue

6. These Counterclaims arise under the Patent Laws of the United States, 35 U.S.C. §§ 1 *et seq.*, and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202, based on an actual controversy between Lannett and Plaintiffs/Counterclaim-Defendants Purdue Pharmaceutical Products L.P.; Purdue Pharma L.P.; and Purdue Pharma Technologies Inc. (collectively “Plaintiffs/Counterclaim-Defendants”).

7. This Court has original jurisdiction over the subject matter of these Counterclaims at least under 28 U.S.C. §§ 1331, 1338(a), and 1367, 35 U.S.C. § 271(e)(5), and 21 U.S.C. § 355(j)(5)(C).

8. This Court has personal jurisdiction over Plaintiffs/Counterclaim-Defendants at least because Plaintiffs/Counterclaim-Defendants have subjected themselves to the jurisdiction of this Court.

9. Upon information and belief, Plaintiff/Counterclaim-Defendants are joint owners of the ‘960 patent.

10. The current Orange Book: Approved Drug Products With Therapeutic Equivalence Evaluations” published by the FDA (“the Orange Book”) states that the NDA applicant for Dilaudid® (hydromorphone hydrochloride) oral solution is Purdue Pharmaceutical Products L.P. and that the NDA Number is 19-891. The Patent and Exclusivity Information provided by the Orange Book lists the ‘960 patent.

11. Lannett Holdings, Inc. filed the Lannett ANDA with the FDA seeking approval to market the Lannett Product prior to the expiration of the Orange Book listed ‘960 patent. The Lannett ANDA includes a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) for the ‘960 patent.

12. Lannett Holdings, Inc. sent a letter, *inter alia*, to Plaintiffs/Counterclaim-Defendant Purdue Pharmaceutical Products L.P. pursuant to 21 U.S.C. § 255(j)(2)(B)(i) and/or (ii), informing Plaintiffs/Counterclaim-Defendants of Lannett Holdings, Inc.'s ANDA certification that if it were to manufacture, use, sell, offer to sell, and/or import into the United States the Lannett Product, such acts would not infringe any valid or enforceable claim of the Orange Book-listed '960 patent. Lannett Holdings, Inc. attached to its letter a detailed statement of factual and legal bases which support its certifications for the '960 patent.

13. Within forty-five days of receiving Lannett Holdings, Inc.'s letter, Plaintiffs/Counterclaim-defendants filed the Complaint against Lannett. Plaintiffs/Counterclaim-Defendants allege that a sale, offer for sale, use, or commercial manufacture of the Lannett Product during the terms of the '960 patent would infringe the claims of that patent.

14. Plaintiffs/Counterclaim-Defendants further allege that the submission of the Lannett ANDA constitutes infringement.

FIRST COUNTERCLAIM
(Declaratory Judgment of Non-Infringement of the '960 Patent)

15. Lannett restates paragraphs 1-14 of these Counterclaims as if set forth fully herein.

16. Plaintiffs/Counterclaim-Defendants have alleged that Lannett has infringed and/or will infringe the '960 patent, and Lannett has denied these allegations.

17. As evidenced by Plaintiffs/Counterclaim-Defendants' Complaint and Lannett's Answer and Affirmative Defenses thereto, there is an actual, substantial, and continuing justiciable case or controversy between the parties regarding infringement of the '960 patent.

18. The filing of the Lannett ANDA, the proposed activities of Lannett Holdings under the ANDA, and the Lannett Product have not, and would not, directly or

indirectly infringe any valid and enforceable claim of the '960 patent, either literally or under the doctrine of equivalents.

19. Lannett is entitled to a judicial determination that the filing of the Lannett ANDA, the proposed activities under the Lannett ANDA, and the Lannett Product do not and will not result in infringement of any valid claim of the '960 patent, directly or indirectly, either literally or under the doctrine of equivalents.

SECOND COUNTERCLAIM
(Declaratory Judgment of Invalidity of the '960 Patent)

20. Lannett restates paragraphs 1-19 of these Counterclaims as if set forth fully herein.

21. As evidenced by Plaintiffs/Counterclaim-Defendants' Complaint and Lannett's Answer and Affirmative Defenses thereto, there is an actual, substantial, and continuing justiciable case or controversy between the parties regarding the validity of the claims of the '960 patent.

22. One or more of the claims of the '960 patent are invalid for failure to comply with one or more of the statutory provisions of 35 U.S.C. §§ 101 *et seq.*, including §§ 102, 103, and 112.

23. Lannett is entitled to a judicial determination that one or more of the claims of the '960 patent are invalid for failure to comply with one or more of the statutory provisions of 35 U.S.C. §§ 101 *et seq.*, including §§ 102, 103, and 112.

PRAYER FOR RELIEF

WHEREFORE, Lannett respectfully requests that this Court enter judgment:

- A. Dismissing Plaintiffs' Complaint with prejudice;
- B. Denying Plaintiffs' requested relief;
- C. Finding, declaring, and adjudging that Lannett has not and would not infringe any valid and enforceable claim of the '960 patent;
- D. Finding, declaring, and adjudging that one or more claims of the '960 patent are invalid;
- E. Awarding Lannett its reasonable costs;
- F. Finding this to be an exceptional case under 35 U.S.C. § 285 and awarding Lannett its reasonable attorneys' fees and expenses incurred in this action; and
- G. Granting such other and further relief as this Court may deem just and proper.

Respectfully submitted,

FOX ROTHSCHILD LLP

Dated: December 1, 2015

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*Attorneys for Defendants Lannett Holdings,
Inc. and Lannett Company, Inc.*

LOCAL CIVIL RULE 11.2 CERTIFICATION

Pursuant to Local Civil Rule 11.2, the undersigned attorney for defendants, Lannett Holdings, Inc. and Lannett Company, Inc., certifies that, to the best of his knowledge, the matter in controversy is not the subject of any other action pending in any court or of any pending arbitration or administrative proceeding.

Dated: December 1, 2015

/s/ Joseph F. Posillico
Joseph F. Posillico
jposillico@foxrotshchild.com

CERTIFICATE OF SERVICE

I hereby certify that on December 1, 2015 I caused a true and correct copy of the foregoing Defendants Lannett Holdings, Inc. and Lannett Company, Inc.'s Answer, Defenses, and Counterclaims to be served upon all Counsel of Record *via* the Court's CM/ECF system.

Dated: December 1, 2015

/s/ Joseph F. Posillico
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